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U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ALABAMA NORTHEASTERN DIVISION

ROBERT DANIEL IMBUSCH,	)	
	)	
Plaintiff,	)	
vs.	)	**CIVIL ACTION NUMBER 5:05-cv-01271**
	)	
WYETH PHARMACEUTICALS INC. and AMGEN INC.	)	
	)	
	)	
Defendants.	)	

BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO BIFURCATE DISCOVERY

Defendants Amgen Inc. and Wyeth Pharmaceuticals Inc. (collectively "Defendants") hereby submit this Brief in Support of Defendants' Motion to Bifurcate Discovery. For the reasons discussed below – and consistent with the decisions of every other court that has addressed this precise issue in cases against Defendants relating (as does this case) to the drug Enbrel® – Defendants request that the Court bifurcate discovery and require that plaintiff provide evidentiary support on the critical issue of causation at the outset of this litigation, before any other discovery is permitted.

The entry of such an order is appropriate for several compelling reasons. First, requiring a showing of medical causation now is fair, as plaintiff should have obtained the requested information prior to filing this suit. Second,

notwithstanding his assertion to the contrary, the plaintiff's medical records do not establish a causal relationship between his cardiomyopathy and Enbrel®, and indeed, indicate that the cause of his condition is not entirely known. Third, although the pertinent package insert for Enbrel® properly documented the "rare reports of new onset congestive heart failure [which can be caused by, among other conditions, cardiomyopathy], including congestive heart failure in patients without known pre-existing cardiovascular disease," there is no scientifically-reliable, peer-reviewed literature documenting a causal connection between Enbrel® and cardiomyopathy or congestive heart failure. Fourth, requiring production of causation evidence now will further the Court's gatekeeping function by ensuring that a case lacking factual support for a critical element of liability will not consume the resources of the parties or this Court. Finally, requiring this preliminary showing will not prejudice plaintiff because, assuming he is able to make the requisite showing, discovery will proceed as it would in any other case.

Indeed, in similar cases involving injuries allegedly caused by Enbrel®, federal district courts in Texas, South Carolina, and Louisiana have ruled, as the Defendants are requesting here, that plaintiffs must present evidence of a causal relationship between their injuries and Enbrel® before the litigation would be permitted to proceed to full discovery. See Order Granting Motion to Bifurcate Discovery, Staying Non-Causation Discovery, and Setting Deadline for Summary-

Judgment Motion Regarding Causation (filed Dec. 17, 2003), Hahn v. Amgen Inc., et al., Action No. 4:03-CV-855-Y (N.D. Tex.) (attached as Exhibit A); Transcript of Dec. 16, 2003 Motion Hearing, Parker, et al. v. Amgen Inc., et al., No. 4:02-CV-3286 (D.S.C.) (attached as Exhibit B); Order (filed Aug. 15, 2003), Diamond, et al. v. Immunex Corp., et al., Docket No. 2:03-CV-564 (W.D. La.) (attached as Exhibit C). In addition, a state trial court in New Jersey has come to the same conclusion. See Transcript of Oct. 14, 2004 Motion Hearing, Cerchio, et al. v. Amgen Inc., et al., No. L-2857-04 (N.J. Super. Law Div.) (attached as Exhibit D). Furthermore, another federal district court, in Pompey v. Immunex Corp., et al., Docket No. 2:04-CV-03357 (E.D. La.), recently approved the parties' Rule 26(f) proposed scheduling order, which set forth an agreed-upon bifurcated discovery schedule, similar to what Defendants are requesting here. A copy of the Order is attached as Exhibit E.

In short, no court presented with this issue has ruled to the contrary, and for the reasons outlined below, Defendants urge this Court to grant the Defendants' motion.

I. BACKGROUND

A. Enbrel® and the Medical Literature

Enbrel® (etanercept) is a prescription biologic product approved by the United States Food and Drug Administration ("FDA") in November 1998 for the

treatment of rheumatoid arthritis. See http://www.fda.gov/cder/biologics/products/etanimm110298.htm.[1] In his lawsuit, plaintiff alleges that – as a result of using Enbrel®[2] – he developed cardiomyopathy.[3] Although plaintiff correctly alleges that the package insert for Enbrel® documents the rare reports of new onset congestive heart failure, including congestive heart failure in patients without known preexisting cardiovascular events, the package insert does not state that Enbrel® caused these instances of congestive heart failure. Moreover, plaintiff can find no refuge in the

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[1] Subsequent to this approval, the FDA has approved Enbrel® for a number of other uses. See e.g., http://www.fda.gov/cder/biologics/products/etanimm052799.htm (juvenile rheumatoid arthritis); http://www.fda.gov/cder/biologics/products/etanimm011502.htm (psoriatic arthritis); http://www.fda.gov/bbs/topics/ANSWERS/2003/ANS01240.html (ankylosing spondylitis); http://www.fda.gov/cder/biologics/products/etanimm060600.htm (inhibition of structural damage associated with moderate to severely active rheumatoid arthritis); http://www.amgen.com/media/media_pr_detail.jsp?year=2004&releaseID=521767 (plaque psoriasis).

[2] Enbrel® inhibits tumor necrosis factor ("TNF"), which is a chemical messenger that helps regulate the inflammatory process. During a normal immune response, TNF attaches to special cells throughout the body, and activates immune cells. This activation causes immune cells to release chemicals that can contribute to inflammation. In patients with psoriatic arthritis, such as Imbusch, excessive TNF is produced by the body, and the body's immune system cannot adequately control inflammation in the joints, resulting in a thinning of the cartilage and accompanying pain. Enbrel® is similar to a protein produced naturally by the body that can bind to some of the excess TNF molecules and deactivate them before they trigger inflammation. By interrupting the chain of events that leads to inflammation, Enbrel® reduces inflammatory symptoms.

[3] Cardiomyopathy is a disease of the heart muscle that causes the heart muscle to become inflamed, which impacts the heart's ability to pump properly. It can be caused by a number of factors. Although cardiomyopathy is one of many causes of congestive heart failure, cardiomyopathy does not always result in congestive heart failure.

available medical literature, which is devoid of even a single article that concludes that Enbrel® causes congestive heart failure.

For example, in one peer-reviewed article, the authors examine adverse event reports of "heart failures" submitted to the United States Food and Drug Administration's MedWatch program, which receives reports of adverse events related to FDA-licensed products after the products are marketed to the general population. Hyon J. Kwon, et al., Case Reports of Heart Failure After Therapy with a Tumor Necrosis Factor Antagonist, 138 ANNALS INTERNAL MED. 807, 807 (2003) (a copy of which is attached as Exhibit F). The use of this broad search term, which includes various cardiac conditions and is a common diagnosis listed in a discharge summary, generated forty-seven reports of various types of heart failures for patients treated with Enbrel® as well as another TNF-inhibitor, Remicade®, which is manufactured by Centocor. Id. at 807-08. After examining these reports, the authors explained that "these spontaneous reports alone are not sufficient to make casual inferences." Id. at 810. Further, they noted that the underlying conditions of the forty-seven patients "may have contributed to heart failure in some older patients." Id. Finally, the authors explained that "it is possible that some of these reported heart failure events occurred by chance." Id. Thus, the authors concluded that there was no basis to believe that there was a causal relationship between new onset heart failure (or exacerbation of preexisting

heart failure) and TNF antagonist therapy. Id. In light of peer-reviewed literature such as this, it is highly unlikely that plaintiff will be able to establish to a reasonable degree of medical certainty that his cardiomyopathy was caused by Enbrel®.

Additionally, in March 2003, the FDA Arthritis Advisory Committee ("Committee" or "AAC") decided against recommending a label change to suggest any causal association between congestive heart failure ("CHF") and TNF-alpha antagonists. Specifically, on March 4, 2003, the Committee held a meeting entitled "Safety Update on the TNF-α Blocking Agents." Among the topics addressed was the question of whether it was reasonable to discuss CHF-related safety concerns in the labels for TNF blocking agents such as Enbrel®. See Questions for March 4, 2003 AAC Meeting, available at http://www.fda.gov/ohrms/dockets/ac/03/questions/3930Q1.htm. The information provided to the panel by Abbott Laboratories, Amgen Inc. and Centocor Inc., who respectively manufacture the TNF-blocking agents Humira™ (adalimumab), Enbrel® (etanercept) and Remicade® (infliximab), as well as outside consultants, demonstrated that the patterns of new-onset CHF occurrence in the population treated with TNF inhibitors is similar to that which is observed in the rheumatic disease population. See Transcript of Mar. 4, 2003 AAC Meeting at 88, 141-42, 313, available at http://www.fda.gov/ohrms/dockets/ac/03/transcripts/3930T1.pdf.

Based upon this data, the Committee did not recommend any label change to suggest any causal association. Id. at 330. The decision of the Committee adds strong support to the conclusion that it is highly unlikely that plaintiff can make even a threshold showing that plaintiff's cardiomyopathy, which can be a cause of heart failure, was, more likely than not, caused by his use of Enbrel®.

In the face of such strong medical evidence to the contrary, plaintiff should be required to produce expert causation evidence, if he can, before valuable court resources, and the resources of the parties, are expended in this case, where there is a strong likelihood that plaintiff will not be able to produce admissible causation evidence in support of his claim.

B. Summary of Plaintiff's Pertinent Medical Information

Plaintiff has psoriasis and psoriatic arthritis. Compl. ¶¶ 5-6. He was treated with Enbrel® for less than four months, from June 24, 2004 until about October 1, 2004. Compl. ¶¶ 17, 20; See Record of Dr. Lee (Oct. 1, 2004), a copy of which is attached as Exhibit G. In September of 2004, he was diagnosed with cardiomyopathy. See Record of Dr. Lee (Sept. 20, 2004), a copy of which is attached as Exhibit H.

While plaintiff alleges that Enbrel® caused his cardiomyopathy, the only specific factual allegations in the Complaint addressing this alleged causal connection is the inaccurate statement that "[a]t the time of diagnosis, Plaintiff's

treating cardiologist attributed Plaintiff's Enbrel treatment as a likely cause of his condition." Compl. at ¶ 21. However, an examination of plaintiff's medical records demonstrates clearly that this allegation is incorrect. Indeed, the records of plaintiff's treating cardiologist, Dr. James Lee, indicate that plaintiff had a consultation for cardiomyopathy and chest pains on September 20, 2004, and Dr. Lee noted that the patient "has new chest pains for which the etiology is not entirely clear." See Sept. 20, 2004 Record (Ex. H). With respect to plaintiff's cardiomyopathy, the record indicates that Dr. Lee asked plaintiff to bring in the package insert for Enbrel® because Dr. Lee did not know whether it was an immunomodulator, which may have made plaintiff "more prone to develop a viral myocarditis." See id. Thus, the notes from the date on which plaintiff was seen by a cardiologist for his cardiomyopathy do not establish that his condition was caused by Enbrel®.

Similarly, the record from plaintiff's subsequent visit with Dr. Lee on October 1, 2004, note that plaintiff "has nonischemic cardiomyopathy possibly secondary to Enbrel therapy." See Oct. 1, 2004 Record (Ex. G). Clearly, the notation of a possible link does not establish the causal relationship suggested by the plaintiff in the Complaint.

Moreover, to the extent that plaintiff argues that Enbrel® was an immunomodulator, which made him more prone to develop a viral myocarditis –

an argument Defendants believe is unsupported – such reliance would be misplaced because plaintiff has taken at least one other pharmaceutical product – Methotrexate – which is also an immunomodulator that suppresses the immune system and decreases resistance to infection. See Product Label Details in Conventional Order for Methotrexate, available at http://www.accessdata.fda.gov/scripts/cder/onctools/labels.cfm?GN=methotrexate (listing decreased resistance to infection in the "Adverse Reactions" section).

For all of these reasons, Defendants believe that it is unlikely that plaintiff will be able to produce a valid, scientifically reliable expert opinion that Enbrel® was the cause of plaintiff's cardiomyopathy.

II. REQUIRING A THRESHOLD SHOWING OF MEDICAL CAUSATION IS WARRANTED IN THIS CASE

An order requiring plaintiff to make a threshold showing of medical causation is entirely appropriate. Indeed, it is important to note that federal district courts have nearly unfettered discretion to control the timing and scope of discovery. See, e.g., Amey, Inc. v. Gulf Abstract & Title, Inc., 758 F.2d 1486, 1505 (11th Cir. 1985) ("A trial court has wide discretion in determining the scope and effect of discovery."), cert. denied, 475 U.S. 1107 (1986). Moreover, "Rule 26 vests the trial judge with broad discretion to tailor discovery narrowly and to dictate the sequence of discovery." Crawford-El v. Britton, 523 U.S. 574, 598-99 (1998) (noting that "the court may postpone all inquiry" regarding certain matters

"until discovery has been had on objective factual questions such as whether the plaintiff suffered any injury"). Id. at 599. Therefore, this Court clearly has the discretion to bifurcate discovery. See e.g., Adams v. Thiokol Corp., 231 F.3d 837, 841 (11th Cir. 2000) (noting that the district court bifurcated discovery to examine the denial of severance benefits before allowing general discovery on whether plaintiffs' new employment was comparable, and other matters).

In addition, an order bifurcating discovery is particularly appropriate in this case because, as described above, it is unlikely that plaintiff will be able to sustain his burden of demonstrating that his cardiomyopathy (which can be a cause of heart failure) was, more likely than not, caused by his use of Enbrel®. As detailed above, the medical literature, the AAC's review of relevant data, and plaintiff's own medical records suggest strongly that medical causation is a not a legal hurdle the plaintiff will be able to overcome.

A. Bifurcation Is Efficient and Will Conserve Court Resources

A finding of medical causation is critical to any finding of liability under all the causes of action alleged by plaintiff.[4] Full discovery on all issues potentially

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[4] See, e.g., Bell v. T.R. Miller Mill Co., Inc., 768 So. 2d 953, 957 (Ala. 2000) (stating that in order to establish liability under the AEMLD, plaintiff must show that "that which caused the product to be in such an unfit condition in fact caused the injury"); B E & K, Inc. v. Weaver, 801 So. 2d 12, 19 (Ala. Civ. App. 2000) (misrepresentation requires "a causal connection between the false representation and the injury"); Frank Crain Auctioneers, Inc. v. Delchamps, 797 So. 2d 470, 473 (Ala. Civ. App. 2000) (to recover for fraud, plaintiff is required to prove "that he suffered damages because of his reliance" on the alleged fraud); Gean v. Cling Surface Co., 971 F.2d 642, 645 (11th Cir. 1992) (proximate causation – "not merely a 'remote' cause" is a

relevant under Alabama law will be very expensive and time consuming. Before the parties and the Court embark on full discovery on issues that may never need to be addressed, plaintiff should be required to provide a valid, admissible expert opinion on the critical issue of medical causation.[5] Requiring such a showing is particularly warranted in the instant case where plaintiff's allegations suggesting a causative link between his alleged injuries and his use of Enbrel® are inconsistent with the medical records and the medical literature.

Equally important, requiring production of the information now will serve to ensure that a case lacking factual support for a critical element of liability will not consume the resources of this Court or the parties. Also – in the unlikely event that plaintiff succeeds in making the requisite showing – requiring preliminary proof of causation will also streamline and focus future discovery.

B. The Federal Rules Require Plaintiff To Have This Information Already

Requiring such a showing now is fair and will not present an undue burden on plaintiff because the Order Defendants seek merely requires the production of

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required element of a failure to warn claim) (citation omitted); Wal-Mart Stores, Inc. v. Langham, 794 So. 2d 1170, 1172 (Ala. Civ. App. 2001) ("Absent a showing of proximate causation, Langham failed to establish a prima facie case of . . . wantonness.").

[5] Of course, any expert opinion that does not comply with Daubert v. Merrell Dow Pharmaceuticals., Inc., 509 U.S. 579 (1993), and other relevant authority simply would not be valid.

information plaintiff is required, under Rule 11(b)(3), to have had before filing.[6] Plaintiff should have had at least some basis for alleging that the named Defendants are responsible for his injuries.

C. The Requested Order Is Similar To Lone Pine Orders Issued In Other Cases

Discovery management orders of the type requested here are often referred to as "Lone Pine orders," named for the court's decision in Lore v. Lone Pine Corp., No. L-33606-85, 1986 WL 637507 (N.J. Super. Ct. Law Div. Nov. 18, 1986) (attached as Exhibit I). In Lone Pine, the trial court entered case management orders requiring the plaintiffs to produce "the basic facts" supporting their claims of personal injury and property damage, including "[r]eports of treating physicians and medical or other experts, supporting each individual plaintiff's claim of injury and causation by substances from Lone Pine Landfill." Id. at *1-*2.

Numerous courts have recognized that Lone Pine orders are useful to assist in streamlining and managing litigation, particularly where – as here – the plaintiff's ability to establish that their injuries were caused by exposure to a

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[6] Fed. R. Civ. P. 11(b)(3); see also, e.g., Battles v. City of Ft. Myers, 127 F.3d 1298, 1300 (11th Cir. 1997) (holding not abuse of discretion to impose sanctions on attorney where claims asserted lacked evidentiary support).

harmful substance is in doubt.[7] In fact, as noted above, federal and state trial courts in four similar cases involving injuries allegedly caused by Enbrel® have required plaintiffs to present evidence of a causal relationship between their alleged injuries and Enbrel® before the their suits could go forward. See Order Granting Motion to Bifurcate Discovery, Staying Non-Causation Discovery, and Setting Deadline for Summary-Judgment Motion Regarding Causation (filed Dec. 17, 2003), Hahn v. Amgen Inc., et al., Action No. 4:03-CV-855-Y (N.D. Tex.) (Ex. A); Transcript of Dec. 16, 2003 Motion Hearing, Parker, et al. v. Amgen Inc., et al., No. 4:02-CV-3286 (D.S.C.) (Ex. B); Transcript of Oct. 14, 2004 Motion Hearing,

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[7] See, e.g., Acuna v. Brown & Root Inc., 200 F.3d 335, 340-41 (5th Cir. 2000) (upholding district court's Lone Pine order requiring that, before discovery could proceed, plaintiffs produce, inter alia, an affidavit from a qualified expert opining that the plaintiffs' injuries were more probably than not caused by exposure to the substance); Claar v. Burlington N. R.R., 29 F.3d 499, 500 (9th Cir. 1994) (noting that district court, concerned that plaintiffs might not be able to make a causal connection between their workplace chemical exposure and their injuries, issued a case management order requiring, among other things, that plaintiffs submit affidavits from physicians listing the scientific basis for the physicians' opinion that the injuries were caused by exposure to the chemical); Scheduling Order of Mar. 3, 2003, In Re: 2000 ExxonMobil Release Litigation, Master Docket No. 00-MD-1-C (M.D. La.) (entering Lone Pine order directing plaintiffs to produce, among other things, an affidavit of a qualified treating or other physician identifying the substance to which exposure is claimed, the diagnosis of the plaintiff's alleged injury, and stating to a reasonable medical probability that the injury was caused by exposure to the substance) (attached as Exhibit J); Order of May 31, 1996, Turner v. Firestone Tire & Rubber Co., No. 5-95V-152 (E.D. Tex.) (ordering that each plaintiff file an affidavit from medical or other qualified expert stating that, to a reasonable degree of medical probability, the plaintiff's injuries were caused by exposure to a particular substance) (attached as Exhibit K); Schelske v. Creative Nail Design, Inc., 933 P.2d 799, 804-05 (Mont. 1997) (affirming grant of summary judgment in product liability case where plaintiffs did not comply with case management order requiring production of expert testimony on causation before full discovery could proceed); Cottle v. Superior Court, 5 Cal. Rptr. 2d 882, 890-94 (Ct. App. 1992) (affirming order excluding evidence based on failure of plaintiffs to make prima facie showing of causation).

Cerchio, et al. v. Amgen Inc., et al., No. L-2857-04 (N.J. Super. Law Div.) (Ex. D); Order (filed Aug. 15, 2003), Diamond, et al. v. Immunex Corp., et al., Docket No. 2:03-CV-564 (W.D. La.) (Ex. C). And in one additional case, plaintiff's counsel agreed to the court's entry of such an Order. See Order, Pompey v. Immunex Corp., et al., Docket No. 2:04-CV-03357 (E.D. La.) (Ex. E).

Notably, in ruling that discovery would be bifurcated, Judge Houck in the Parker case made the following observations to plaintiffs' counsel, which are equally applicable to the instant matter:

> You've either got a case or you don't have a case. If you can't relate the drug to your client's condition, then you don't have a case. So why not cross that hurdle to begin with? The defendant says – and I don't have any reason to disbelieve, and I don't see anything where you contradict it – that the doctors that have treated the plaintiff have said that there was no causal connection.
>
> And in light of that, it seems to me that it would be foolhardy to engage in full-blown, expensive discovery and end up with not having a case entirely.

Transcript of Dec. 16, 2003 Motion Hearing in Parker at 2-3 (Ex. B) (emphasis added).

Moreover, in the Cerchio case, Judge Hurley noted that he "generally get[s] this motion from the plaintiff not from the defendant, because the plaintiff wants to save her money." Transcript of Oct. 14, 2004 Motion Hearing, Cerchio, at 46 (Ex.

D). Similar to Judge Houck, Judge Hurley also questioned plaintiffs' counsel on this issue:

> why would we not concentrate on causation and save some time and money here if there is not going to be someone who is going to come in with the requisite testimony and to say that there is a causal relationship, there's a nexus between this product and the injury?

Id. at 43.

As in Hahn, Parker, Cerchio, Diamond and the numerous other cases cited above, plaintiff should be required to make a threshold showing by way of an admissible expert opinion that his alleged injury was, to a reasonable degree of medical certainty, caused by the product at issue – Enbrel®.

III. CONCLUSION

For all of the foregoing reasons, before plaintiff can proceed with discovery in full, he should be required to produce one or more qualified physicians or other experts who can proffer an admissible expert opinion, to a reasonable degree of medical probability, that plaintiff's use of Enbrel® was the direct and proximate cause of his injuries. As such, Defendants request that discovery be bifurcated and that the attached Order (Exhibit L) be entered in this case.

Dated: September 8, 2005

Respectfully Submitted,

s/Thomas Thagard

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing has been served upon the following counsel of record to this proceeding by electronic mail and by placing a copy of same in the United States Mail, properly addressed and postage prepaid this 8th day of September, 2005:

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